**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF TEXAS**
**FORT WORTH DIVISION**

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| OUTSOURCING FACILITIES ASSOCIATION and NORTH AMERICAN CUSTOM LABORATORIES, LLC d/b/a FARMAKEIO CUSTOM COMPOUNDING,<br><br>Plaintiffs,<br><br>v.<br><br>UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. ROBERT M. CALIFF,<br><br>Defendants, and<br><br>ELI LILLY AND COMPANY,<br><br>Intervenor-Defendant. | CASE NO. 4:24-cv-953-P |

**DEFENDANT-INTERVENOR ELI LILLY AND COMPANY'S RESPONSE TO JOINT MOTION TO REOPEN CASE AND ENTER SCHEDULING ORDER**

Defendant-Intervenor Eli Lilly and Company ("Lilly") submits this response to the other parties' joint filing [ECF No. 38], made before the Court allowed Lilly to intervene, to request that the Court set an expedited briefing schedule that allows for the timely resolution of this case. Although Lilly proposed this schedule to the Plaintiffs on January 6, it has not received a response and so notifies the Court of its position in advance of the hearing to aid in efficient consideration.

While the Outsourcing Facilities Association ("OFA") and FarmaKeio Custom Compounding ("FarmaKeio") (collectively, "Plaintiffs") may benefit from delay given Defendant FDA's commitment not to take action against Plaintiffs during the pendency of a preliminary injunction, time is of the essence. FDA first determined that Lilly's tirzepatide products Mounjaro® and Zepbound® were not in shortage on October 2, 2024. ECF No. 1-2, at 2. Plaintiffs

concede that, even under their legal interpretation, they are not permitted to sell their unapproved knockoffs of Mounjaro® and Zepbound® in the absence of a shortage and allege that they must stop such unlawful activities in light of FDA's determination. ECF No. 1, ¶¶ 48–49. FarmaKeio has nevertheless continued to make its unapproved knockoffs for months based on FDA's commitment "not [to] take action against Plaintiffs and their members for violations of the [FDCA] arising from conditions that depend on tirzepatide's inclusion on the drug shortage list." ECF No. 27, at 3. FDA made that commitment in October 2024 to ensure it had the time to carefully evaluate whether the shortage has been resolved. On December 19, 2024, FDA determined that the shortage was resolved but issued a grace period of 60 days for 503A compounders (like FarmaKeio) and 90 days for 503B outsourcing facilities. FDA expressly acknowledged that these periods exceeded the grace periods provided in its guidance documents and that a lengthy period of non-enforcement would not be appropriate. ECF No. 32-1, at 11. Nevertheless, FDA again committed in this case to "continue to exercise such enforcement discretion through the Court's resolution of [a] motion [for preliminary injunction]." ECF No. 32, at 1. Thus, while entities like FarmaKeio have no lawful right to make or sell copies of Lilly's medicines, they have already benefitted from a *de facto* injunction of over three months and obtained an extended grace period following the December 19 order; for Plaintiffs themselves, the grace period seemingly remains running indefinitely until resolution of their upcoming motion.

"A preliminary injunction is an extraordinary equitable remedy that is never awarded as of right"; it requires a plaintiff to "make a clear showing" that they are entitled to one under the traditional four-factor standard. *Starbucks Corp. v. McKinney*, 602 U.S. 339, 345 (2024) (cleaned up). Thus, Plaintiffs should not receive the benefit of a preliminary injunction, beyond the already extended, generous, and generally applicable non-enforcement period, without making the

necessary showing. Given the status quo and to align the case with FDA's grace period, Lilly believes it is essential to expedite the resolution of this case. The other parties' proposed briefing schedule, however, does not even begin until the parties submit a protective order and would extend briefing on Plaintiffs' upcoming motion into March, ***over five months*** after FDA determined Lilly's medicines were not in shortage. ECF No. 38, at 2. (requesting that replies be due 52 days after Plaintiffs receive the unredacted Decision Memorandum on or about January 15, 2025).[1]

A lengthy briefing schedule for Plaintiffs' preliminary injunction (or summary judgment) motion will incentivize and embolden Plaintiffs to continue unauthorized and unsafe copying of Lilly's medicines, which could also yield even worse outcomes for patients. FarmaKeio and others have been compounding knockoffs of Lilly's medicines by claiming that the prohibitions in the compounding statutes, and particularly 21 U.S.C. § 353a(b)(1)(D), do not apply during drug shortages. *See, e.g.*, Compl., ECF No. 1, ¶ 20. With the shortage now over, every day they continue compounding is another day that patients are needlessly exposed to untested and unapproved knockoffs of Lilly's medicines, in defiance of the FDCA's express terms.

These are not theoretical risks. As the nation learned during the New England Compounding Center ("NECC") disaster when compounded drugs killed more than 100 Americans and sickened hundreds more,[2] compounding pharmacies like FarmaKeio generally do not follow current good manufacturing practices ("cGMP"), and they generally cannot safely

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[1] On January 6, 2025, the Court proposed converting "Plaintiffs' impending motion for preliminary injunction into a motion for summary judgment" and asked the parties to come to a hearing, now scheduled for January 14, "prepared to discuss any issues it may have with the proposed briefing schedule." ECF No. 51, at 1; ECF No. 52.

[2] Press Release, *Former Owner of Defunct New England Compounding Center Resentenced to 14 Years in Prison in Connection with 2012 Fungal Meningitis Outbreak*, U.S. DEP'T OF JUSTICE (July 7, 2021), https://www.justice.gov/usao-ma/pr/former-owner-defunct-new-england-compounding-center-resentenced-14-years-prison.

manufacture mass quantities of sterile injectables like Mounjaro® and Zepbound®. Allowing such entities to continue compounding unlimited quantities of knock-off tirzepatide (as Plaintiffs ask the Court) risks repeating the NECC disaster. The Court need not take Lilly's word for it: FDA recently warned that it received "more than 215 reports of adverse events with compounded tirzepatide," with "some requiring hospitalization," though the actual number of patients suffering adverse events was almost certainly much higher as "federal law does not require" pharmacies "to submit adverse events to FDA."[3] Inspections have uncovered pharmacies compounding sterile injections—including tirzepatide—under conditions likely to result in contamination.[4] Most alarmingly, FDA specifically cited FarmaKeio in 2022 for using "non-pharmaceutical grade components" and "[n]on-sterilized equipment" to prepare allegedly sterile drugs, and issued a warning letter—that appears to be unresolved—for "serious deficiencies in . . . practices for producing drug products intended or expected to be sterile, which put patients at risk."[5] Despite these unresolved issues, FarmaKeio claims it earns "approximately $1,750,000 to $2,000,000 . . . ***per month***" from compounding unapproved tirzepatide drugs that are expected to be sterile. ECF No. 8, at 19–20. Unsurprisingly, leading U.S. health organizations and foreign governments have

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[3] *FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss*, U.S. FOOD & DRUG. ADMIN. (Dec. 18, 2024), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

[4] FDA warns patients and health care professionals not to use compounded drugs from Fullerton Wellness, U.S. FOOD & DRUG. ADMIN. (Nov. 1, 2024), https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-professionals-not-use-compounded-drugs-fullerton-wellness.

[5] Form FDA 483 to N. Am. Custom Labs., LLC d/b/a FarmaKeio Superior Custom Compounding, 6 (Mar. 10, 2022), https://www.fda.gov/media/160771/download; *E.g.*, Warning Letter from Div. of Pharma. Quality Op. II to J. Graves, Vice President, N. Am. Custom Labs., LLC d/b/a FarmaKeio Superior Custom Compounding (Nov. 18, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/north-american-custom-laboratories-llc-dba-farmakeio-superior-custom-compounding-642792-11182022.

urged patients to avoid compounded tirzepatide, including because of "uncertainty about their content, safety, quality, and effectiveness."[6]

Indeed, in resolving the tirzepatide shortage, FDA recognized that "compounded drugs have not undergone FDA premarket review for safety, effectiveness, and quality, and lack a premarket inspection and finding of manufacturing quality that is part of the drug approval process." ECF No. 32-1, at 11. And "drug products that meet the conditions under section 503A are not subject to CGMP requirements and are subject to less robust production standards that provide less assurance of quality." *Id.* For these reasons and others, FDA recognized that "an indefinite or overly long period of enforcement discretion for continued compounding of drugs that may be essentially copies of an approved drug that is no longer in shortage would not be appropriate." *Id.* Based on that judgment, FDA decided to begin enforcing the FDCA against Section 503A state-licensed pharmacies on February 17 and Section 503B outsourcing facilities on March 19. *Id.*, at 10.

FDA developed this 60/90-day grace period "to avoid unnecessary disruption to patient treatment and to help facilitate an orderly transition." *Id.*, at 10. In doing so, FDA acknowledged that this enforcement delay ***already*** "is longer than the period previously described in FDA's guidance documents" when medicines are removed from the shortage list. *Id.*, at 11.

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[6] Press Release, *The American Diabetes Association Announces Statement on Compounded Incretin Products*, AM. DIABETES ASS'N (Dec. 2, 2024), https://diabetes.org/newsroom/press-releases/american-diabetes-association-announces-statement-compounded-incretin#; *Leading Obesity Expert Organizations Release Statement to Patients on Compounded GLP-1 Alternatives*, OBESITY MED. ASS'N (Jan. 8, 2024), https://obesitymedicine.org/blog/leading-obesity-expert-organizations-release-statement-to-patients-on-glp-1-compounded-alternatives/; Press Release, *Protecting Australians from unsafe compounding of replica weight loss products*, DEP'T OF HEALTH & AGED CARE (May 22, 2024), https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protecting-australians-from-unsafe-compounding-of-replica-weight-loss-products; Press Release, *SAHPRA's Position On GLP1 And GIP-GLP1 Products That Are Compounded, Substandard And Falsified*, S. AFRICAN HEALTH PRODS. REGULATORY AUTH. (Nov. 8, 2024), https://www.sahpra.org.za/news-and-updates/sahpras-position-on-glp1-and-gip-glp1-products-that-are-compounded-substandard-and-falsifiedas/.

Lilly submits that the parties should endeavor to complete preliminary injunction or summary judgment briefing by February 17, consistent with the FDA's determination that it provides sufficient time for an orderly transition of patients away from compounded products to FDA-approved medicines. Anything else will result in an "overly long period of enforcement discretion for continued compounding" that "would not be appropriate"—particularly given this 60/90 day extension is on top of the 60-day enforcement reprieve they already received while FDA reconsidered and reaffirmed its determination. *See id.* at 10.

Therefore, Lilly proposes the following schedule for preliminary injunction (or summary judgment) briefing.

| Event | Deadline |
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| Plaintiffs' motion for preliminary injunction or summary judgment | Tuesday, January 21, 2025 |
| Defendants' and Lilly's responses to Plaintiffs' motion for preliminary injunction or summary judgment | Friday, February 7, 2025 |
| Plaintiffs' reply in support of motion | Friday, February 14, 2025 |
| Hearing | As soon as possible thereafter |

This schedule allows sufficient time to brief the issues *and* completes briefing before February 17.

To the extent FDA believes it can produce the full administrative record and Plaintiffs believe they could file a summary judgment motion on this schedule, Lilly has no objection to converting the motion into one for summary judgment. However, should conversion require extending a briefing schedule beyond the February 17 enforcement date, then the conversion would inappropriately confer on Plaintiffs a functional preliminary injunction without them having made the requisite showing required by law. *See, e.g.*, *Starbucks Corp.*, 602 U.S. at 345–46. Accordingly, Lilly respectfully requests the Court to enter a schedule that would ensure that Plaintiffs' challenge to FDA's decision resolving the tirzepatide shortage is fully briefed by February 14, 2025, whether on a motion for summary judgment or for preliminary injunction,

which would ensure that patients receive FDA-approved medicine that is proven safe and effective and Plaintiffs do not improperly receive an "overly long period of enforcement discretion." ECF No. 32-1, at 11.

Dated: January 13, 2025

Respectfully submitted,

*/s/ Dee J. Kelly, Jr.*

Dee J. Kelly, Jr.
State Bar No. 11217250
KELLY HART & HALLMAN, LLP
201 Main Street, Suite 2500
Fort Worth, TX 76102
Telephone: (817) 332-2500
Facsimile: (817) 878-9280
dee.kelly@kellyhart.com

Paul D. Clement (*pro hac vice*)
Erin E. Murphy (*pro hac vice*)
Matthew Rowen (*pro hac vice*)
CLEMENT & MURPHY, PLLC
706 Duke Street,
Alexandria, VA 22314
Telephone: (202) 742-8900
paul.clement@clementmurphy.com
erin.murphy@clementmurphy.com
matthew.rowen@clementmurphy.com

James F. Hurst, P.C. (*pro hac vice*)
Diana M. Watral, P.C. (*pro hac vice*)
Ryan Moorman, P.C. (*pro hac vice*)
James R.P. Hileman (*pro hac vice*)
KIRKLAND & ELLIS LLP
333 West Wolf Point Plaza
Chicago, Illinois 60654
Telephone: (312) 862-2000
Facsimile: (312) 862-2200
james.hurst@kirkland.com
diana.watral@kirkland.com
ryan.moorman@kirkland.com
james.hileman@kirkland.com

Jay P. Lefkowitz, P.C. (*pro hac vice*)
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, New York 10022
Telephone: (212) 446-4800
lefkowitz@kirkland.com

*Attorneys for Defendant-Intervenor*
*ELI LILLY AND COMPANY*

**CERTIFICATE OF SERVICE**

I hereby certify that on January 13, 2025, I served the foregoing document electronically in accordance with the Federal Rules of Civil Procedure.

*/s/ Dee J. Kelly, Jr.*
Dee J. Kelly, Jr.